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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,894	03/09/2004	Joachim Brendel	DEAV2003/0023 US NP	2872

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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
12/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/796,894	BRENDEL ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The final action dated 07/23/08 is being remailed because the examiner has, upon reconsideration, changed his position regarding the allowability of the claimed subject matter. The statutory period for response is hereby reset and will begin to run from the mailing date of this action.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1-7 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al (US 6,531,495, '495, filed Oct 30, 2000, granted 3/11/2003), in view of Smith et al (US Pregrant Pub 2002/0161018).

This rejection is maintained.

Examiner showed '495 teaches in claims 1 and 15 the composition which reads on the elected specie and an effective amount of an IKr channel blocker (see claim 15). '495 does not teach ibutilide as the specific IKr channel blocker or administration sequences. Smith et al teaches the IKr channel blocker, Ibutilide. At paragraph 25, teaches "ibutilide … may enhance the potency of local anesthetics by blocking the IKr channel," thereby placing ibutilide in the category of IKr channel blockers.

Therefore, one of ordinary skill in the art would recognize that when making a composition according to '495, it would be obvious to use a known IKr channel blocker, such as taught in Smith et al where an IKr channel blocker is called for. Additionally, any sequencing of the composition administration is obvious where claim 7 is directed to all possible sequences, i.e. simultaneous, separate, and sequential.

Applicants respond by suggesting super-additive results make the combination unobvious.

Where synergism is claimed, sufficient evidence must be provided to justify the scope of the subject matter recited. See MPEP 716.02(d) and In re Kollman, 201 USPQ 193 (C.C.P.A. 1979) which states for an assertion of synergy to overcome a 103 rejection, not only must the results show a synergistic result, but the evidence must demonstrate a pattern of synergy over the entire range claimed.

Here, the compounds and the dosage (range and form) shown to have supper-additive effect are narrower than the instantly claimed genus of compounds and non-limited dosage range.

It appears the results in the specification at Tables 1 and 2 demonstrate supper-additive effect for increasing theatrical refectory periods when the administration is intravenously administered at 6 mg of the compound of example 1 per kg of bodyweight over 120 minutes, where after 60 minutes 0.12 mg/kg of ibutilide (or 10 micrograms dofetilide) per kg/hr was additionally administered for the period of 60 minutes (page 29 lines 21-25 and pg 31 lines 13-18) in the remodeled animal (goat) model.

It is also noted that the compound of Example 1 alone, when administred at 10 mg per kg body weight per hour brings about a cardioversion in goats (pg 37 lines 8-19). The administration of either 2mg/kg of ibutilide per kilogram of bodyweight or 10 micrograms of dofetilide alone does not appear to show the ability to bring about carioversion in goats (Tables 3 and 4 where 0mg/kg/hr of compound of Example 1 are administered).

The specification appears to assert that cardioversion unexpectedly occurs when the lower doses of 0.3 mg/kg/hr to 3 mg/kg/hr of compound of Example 1 is administrated with 2mg/kg of ibutilide in goats (pg 37 lines 8-17). Similarly, the specification appears to assert cardioversion appears to occur unexpectedly when the lower dose of 3mg/hg/hr of compound of Example 1 is administered with 10 micrograms/kg of dofetilide in goats (pg 37 lines 19-27).

Examiner notes that Table 3 shows 10mg/kg/h dosage shows carioversion at 42 and 50 minutes, which are before the administration of ibutilide. Yet Table 4 shows cariodversion occurring at 83 and 83.3 minutes, which is after the administration of dofetilide. It is unclear why the two do not have similar results where the first 60 minutes should have similar results, given the second agent is not administered until after the first 60 minute period.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Patent Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612